maltitol composition by controlling the maltotriitol content of the maltitol syrup in the preparation of crystalline maltitol.

32. Modified maltitol crystals which crystalline form is determined by controlling the maltotriitol content of the maltitol syrup in the preparation of said crystals. --

REMARKS

VARIOUS AMENDMENTS

(Points 1, 2, 5-6 of the office action)

Claim 7 is amended so as to avoid the reference to both claims 1 and 4.

British spelling of terms has been deleted and replaced without prejudice by English spellings : « crystallising » has been replaced by -- crystallizing -- in claims 3 and 6, « crystallised » has been replaced by -- crystallized -- in claim 9.

The terms "characterised by the fact that" and "characterised in that" have been deleted in claims 1-9 and replaced without prejudice by proper wording.

The term "including" has been deleted and replaced by the term -- comprising -- in claims 1, 2, 5 and 7.

The term "consists in" has been deleted and replaced by the term -- comprising -- in claims 3, 6 and 8.

In claims 2-3 and 5-8, the terms "preferably" and "more preferentially" are deleted. The subject-matter in each case is made the object of a dependent claim.

Claim 9 has been clarified, and in particular the term "directing the form" has been deleted and replaced as suggested by the Examiner, and as it is clear from page 3 lines 3-10 of the specification.

It is believed that claims 1-10 are now clear and definite.

OBJECTIONS UNDER 35 USC 112 §1 (Points 3-4)

It is respectfully submitted that a reduced content of maltosyl-1,6-maltitol is not critical or necessary to the process according to the invention. As stated page 7 lines 21-25 of the specification, a reduced content of maltosyl-1,6-maltitol is advantageously retained, which means that in a preferred embodiment such a reduced content is indeed retained. This does not imply that said reduced content has to be retained in every embodiment.

Such a characteristic is thus not an indispensable feature of the process of the invention, but merely an optional, even though preferable, feature.

Several steps of the process are described on page 9 line 7 through page 14 line 16 of the description. Most relate in fact to particular, sometimes preferred, embodiments of the process of the invention and are thus optional features. Such is the case for example of the reduced content of maltosyl-1,6-maltitol (dealt with hereabove), or the two-stage liquefaction (page 9 lines 23-24), or the use of isoamylase during the saccharification step (page 11 lines 16-17).

In fact, as stated in the description page 11 line 26 through page 12 line 2, the crystallization process per se is known to the person skilled in the art.

The essential feature of the processes of the invention is the one mentioned in the claims as filed, i.e. the fact that the maltitol syrup to be crystallized has a maltitol content greater than or equal to 87 % and a maltotriitol content lower than 1 %, or greater than or equal to 4 %, or between 1 % and 4 %, by weight of dry matter.

The other steps are carried out in compliance with the rules of the art.

The steps of the processes, which are known to the person skilled in the art apart from the characteristic featured in the process claims as filed, have been added to said process claims :

- liquefaction of a starch slurry (page 9 line 8),
- saccharification of the slurry to obtain a maltose hydrolysate containing 87 % by weight of maltose (page 10 line 9-10, page 12 lines 3-4),
- filtration and de-mineralisation of the maltose hydrolysate (page 12 lines 7 and 8),
- hydrogenation of the maltose hydrolysate (page 13 lines 17-18) to obtain a maltitol syrup having a maltitol content greater than or equal to 87% and a maltotriitol content lower than 1 %, or greater than or equal to 4 %, or between 1 % and 4 %, by weight of dry matter,
- crystallisation of the syrup and separation of the formed maltitol crystals (page 14 line 26 for instance).

OBJECTIONS UNDER 35 USC 101 (Points 7-8-9)

Claim 10 has been amended to avoid the recitation of a use.

OBJECTIONS UNDER 35 USC 103(a) (Points 11-12)

Claims 1-3 and 9 rejected as unpatentable over Kataura et al. (EP 741 140)

Kataura et al. describes the production of crystalline maltitol comprising the steps of catalytic hydrogenation of a maltose syrup which a maltose content between 81 and 90 % by weight, and chromatographic separation on a cation exchange resin so as to obtain a maltitol syrup of high purity, said purity being expressed by a maltose content between 94 and 99.9 %.

The Examiner suggests that a maltose content of 99.9 % in the maltose syrup may imply a maltotriitol content of less than 0.1 %.

It must be noted however that Kataura uses solutions which comprise, in addition to DP3, at least glucose and oligosaccharides of a DP higher than 3. After catalytic hydrogenation, the maltitol syrup obtained thus comprises a non-negligible amount of impurities, in particular sorbitol and oligosaccharides alcohols (which is clearly stated in the 13 examples of Kataura).

After purification on a column, the 0.1 to 6 % of impurities will at least comprise sorbitol, other oligosaccharides alcohols of the maltotetraïtol type, or even other impurities (metals, salts, even still a little

isomaltitol, sorbitol, mannitol in relative proportions below or close to 0.1 to 0.2 %, ...)

The Assignee would like to stress the fact that it is generally known to the person skilled in the art that, if the crystalline form of a given compound is a function of its chemical nature (which conditions the parameters of crystalline mesh), it mostly depends on the presence of impurities during the crystallization process of said compound.

It is in fact known that during this crystallization process, it is possible that at least one of the constituents of said impurities may hinder the growth of the crystal and thus modify the morphology, or even completely inhibit the growth. In other words, there will be a molecular interference between the structure of the impurity and the structure of the crystal, and this interference may lead to the partial or total inhibition of the growth of the crystal (for instance leading to the stopping of the development of at least one face of said crystal).

However, if that fact is clearly established, it is not possible to predict the nature of the impurity which may be responsible for this interference (nor the amount of impurities responsible), nor and especially to predict the morphology of the resulting crystal, without extensive research.

As mentioned hereabove, Kataura's maltitol syrups comprise 0.1 to 6 % of impurities. It is thus not at all obvious for the person skilled in the art, even particularly skilled, to expect that the crystalline form which he/she will obtain will automatically be the same crystalline form as that claimed in the present application.

In fact, and contrary to the statement of the Examiner, nothing in Kataura describes nor suggests that the person skilled in the art uses a starting material which is rigorously identical. The mere fact that there is 0.1 % of impurities is not sufficient, since nothing suggests that the impurities are of the same nature as in the present invention, i.e. maltotriitol.

Furthermore, it is well known in the sugar crystallization field that the limit of 0.1 % of impurities is still high enough to generate a variation of crystalline forms of the considered sugar. For example, for the crystallization of saccharose, it has been established that the presence of raffinose in the impurities of a solution to be crystallized, even at a content lower than 0.1 %, leads to an alteration of the growth of the crystal. It has also been established that impurities of another nature, such as dextrane, kestose or traces of glucose/fructose, will have similar effects and will lead to variations in the crystalline morphology.

The Examiner will find an illustration of these statements in the enclosed documents :

- "Sucrose - Properties and Applications", M. Mathlouthi and P. Reiser, 1995, Blackie Academic and Professional,
- "Contribution of ketoses (fructo-oligosaccharides) to the morphological modification of sucrose crystals", Vaccari et al.,
- "Effect of dextran, glucose and fructose on sucrose crystal elongation and morphology", Bubnik et al.

The invention of the present application thus relates non only to the determination of two specific crystalline forms of maltitol, but also to the nature of the impurity (maltotriitol) and also its amount which are responsible for the determined variation of the observed crystalline form.

Claims 4-6 and 9 rejected as unpatentable over Devos et al. (US 4,846,139)

Devos describes the preparation of maltitol crystals from maltitol syrups comprising 2.5 to 13 % by weight of maltotriitol. The Examiner infers that these may be considered as maltitol syrups comprising at least 4 % of maltotriitol, and thus the obtained crystals should have a prismatic form.

The assignee would like to stress that the Devos fractions enriched in maltitol comprise also at least 1.5 % of other impurities in addition to maltotriitol (Cf. the examples).

As explained above, such a quantity of various impurities will obviously lead to numerous and non-determinable crystalline forms. However, nothing in Devos suggests to the person skilled in the art that a specific crystalline form may be obtained using a specific starting material comprising a specific amount of a specific impurity.

On the contrary, the invention of the present application relates to the determination of two specific crystalline forms of maltitol, and the parameter which allows for such a determination.

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In view of the above, it is considered that the application is now in proper form for allowance. Favorable consideration and prompt allowance of these claims are respectfully requested.

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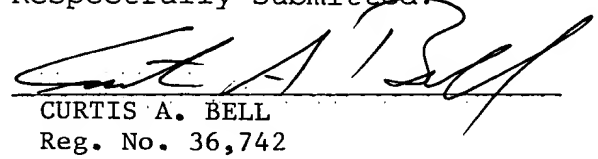
Respectfully submitted,



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